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FY Results 2014: Transcript of video interview with Serge Weinberg, Chairman & Chief Executive Officer

EuroBusinessMedia (EBM): Sanofi, a global and diversified healthcare leader, reports results for 2014. Serge Weinberg, welcome. You are the Chairman and CEO of Sanofi. What are your comments on your 2014 results?

Serge Weinberg: Actually, I am very pleased with our strong performance in 2014. In the last quarter of the year, we were entirely focused on delivering growth, further strengthening innovation and improving execution. Overall, we can look back at 2014 as a successful year. We returned to growth and we delivered financial results in line with our guidance.

Let me point out that, in 2014, both top and bottom line showed growth at constant exchange rates. We delivered sales of 33.8 billion euros for the year, up 4.9% and business EPS of 5.20 euros per share, up 7.3%, both at constant exchange rates.

Importantly, we made significant progress in bringing new medicines to the market. We achieved numerous milestones in our R&D pipeline and we have launched, or we are actively preparing to launch multiple new products.

All in all, I feel confident about the future success of the Group and how we can adapt to an ever changing healthcare environment.

EBM: Where do things stand today on the search for a new CEO? Can you update us on timing, and the type of profile you're looking for?

Serge Weinberg: Well, I was expecting your question and I can assure you that the search for a new CEO is progressing very well.

The Board is making good progress in its search for a strong business leader with a deep understanding of our industry and a broad management experience. Sanofi is an exciting company and we have reviewed a lot of candidates. We are confident that we can make an announcement during the course of the first quarter.

EBM: What are your comments on the performance of Lantus®? What is the outlook for Diabetes in 2015?

Serge Weinberg: Our Diabetes business performed pretty well in 2014 and we have finished the year with double-digit growth. Full-year sales of Lantus® reached 6.3 billion euro, up 12.1%, reflecting a price effect of 7.3% (essentially in the U.S.) and a volume effect of 4.8%.

In the fourth quarter, sales of the Diabetes division increased 11% to 2 billion euro, driven by double-digit growth of Lantus® in the U.S., Emerging Markets and Western Europe. For the full-year, sales of the Diabetes division grew 12.1% to 7.3 billion euros.

In the U.S., Lantus® sold in the SoloSTAR pen represented 61.7% of our overall total Lantus® sales, versus 58% for the same period in 2013. The recent good news is that the market share of Lantus® in the U.S. has stabilized since now 10 weeks. However, the increased rebates in the U.S. and the roll-out of the Affordable Care Act are expected to impact the U.S. outlook of Lantus® in 2015.

Sanofi expects to mitigate this impact on the Diabetes division in 2015 through the launches of Toujeo® and Afrezza® as well as continued strong growth in Emerging Markets.

As you probably know, Afrezza®, the only inhaled insulin, is available in the U.S. since Tuesday. Afrezza® is a drug-device combination product that consists of a dry formulation of human insulin delivered from a small and portable inhaler to help patients achieve blood sugar control. This product is an important addition to Sanofi's growing diabetes portfolio.

Next will be Toujeo®, our new long lasting insulin. We are entering the final stages of the regulatory process. FDA and EMEA decisions for Toujeo® in the U.S. and EU are expected respectively in Q1 and Q2 2015.

EBM: With so many major launches planned in 2015, how do you rate your ability to handle them all successfully at the same time?

Serge Weinberg: 2015 is going to be all about excellence in execution of our launches. Major launches are either ongoing or actively prepared for Cerdelga®, Lemtrada™ in the U.S., Afrezza® in the U.S., Toujeo®, Praluent™ and Dengue Vaccine.

Our success in 2015 will be defined by how well we perform against this strategy. Now, we have got different parts of the organization handling those launches in parallel.

- Genzyme's Rare Disease team is focused on Cerdelga® while Genzyme's MS team is introducing Lemtrada™ in the U.S.
- The launch of Afrezza® by our Diabetes division will occur in two phases and in 2015 we are focused on the U.S. roll-out. As I already mentioned, our Diabetes team is also preparing for the launch of Toujeo®.
- Praluent™ is a potential paradigm shift in the management of patients with high LDL at high cardiovascular risk. The launch preparation is handled by a separate dedicated launch unit.
- Last but not least, the introduction of our Dengue vaccine in some key endemic countries is handled by what we call internally the Dengue Company. This is a dedicated team within Sanofi Pasteur, our Vaccines division.

So, as you can see, we have multiple new product launches across the organization this year. This is clearly an exciting time for Sanofi and we are concentrating our resources behind the success of our new products.

EBM: The FDA has accepted a priority review for your new drug Praluent™. What are the implications, and the outlook, for this product?

Serge Weinberg: Praluent™, or alirocumab, is intended for the treatment of patients with hypercholesterolemia at high cardiovascular risk. This new drug will address a sizable patient population who do not seem to benefit from currently available lipid lowering therapies.

In the U.S., the regulatory application for Praluent™ was accepted at the end of January, as it was announced on January 26th. Under the Prescription Drug User Fee Act, or PDUFA, the goal for a priority review is six months, for a target action date of July 24, 2015.

Earlier in January, we announced that the European Medicines Agency (EMA) did accept the application for Praluent™ in the European Union. The regulatory filing for Praluent™ contains data from more than 5,000 patients, including 10 Phase 3 ODYSSEY trials. Together, with additional ongoing studies including ODYSSEY OUTCOMES, the ODYSSEY clinical trial program will include more than 23,500 patients at more than 2,000 study centers in double-blind, randomized, placebo-and active-controlled trials ranging from 24 weeks to approximately 5 years.

Once approved, Praluent™ has the potential to transform the management of hypercholesterolemic patients with high CV risk. With our partners at Regeneron, we are working hard to ensure launch readiness.

EBM: What is your update on your business in Emerging Markets?

Serge Weinberg: Once again in 2014, we delivered a strong performance in Emerging Markets, nearly reaching double-digit growth, up 9.3%. Clearly, Sanofi remains a leader in Emerging Markets with more than 11 billion euro sales and a market share in that region of well over 5%. The Emerging Markets region represents a third of Sanofi's worldwide sales.

In the fourth-quarter, sales in Emerging Markets were up again, +7.9% to 3.1 billion euros. The economies of these fast developing countries will remain a key growth engine for Sanofi and we have decided to dedicate additional resources to Emerging Markets in order to leverage our leadership position. New initiatives are underway to further expand our footprint in these markets.

EBM: Sanofi has a long tradition of increasing its dividend. What are the prospects for shareholders this year, based on your solid financial results in 2014?

Serge Weinberg: The dividend continues to be a core part of our value proposition to investors. Today, the Board of Directors has proposed to our shareholders a dividend of 2.85 Euros per share for the 2014 fiscal year, which would mark the 21st consecutive year of dividend increases.

This dividend would represent a 5 euro cents increase versus last year and correspond to a payout ratio of 54.8%.

EBM: What is your outlook for 2015?

Serge Weinberg: Taking into account the outlook for U.S. Diabetes as well as new product launches and late stage pipeline development, 2015 business EPS is expected to be stable to slightly growing vs. 2014 at constant average exchange rates, barring major unforeseen adverse events.

I insist here on the fact that this guidance is at constant exchange rates. When applying December 31st, 2014 exchange rates to this Full Year 2015 guidance, the additional positive foreign currency impact on 2015 business EPS is estimated to be between 4% and 5%.

EBM: Serge Weinberg, Chairman and CEO of Sanofi, thank you very much.

Serge Weinberg: Thanks Adrian.